DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, New York 11433-1034

WARNING LETTER

January 25, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2001-36

Albert S. Trachtenberg, M.D.
Chairman, Department of Radiology
St. Charles Hospital & Rehabilitation Center
200 Belle Terre Road
Port Jefferson, New York 11777

Facility ID: #138065

Dear Dr. Trachtenberg:

Your facility was inspected on December 20th, 2000, by a representative of the Suffolk County Department of Health Services, Radiation Control Unit acting on behalf of the U. S. Food & Drug Administration (FDA). We apologize for the delay in agency review of the noncompliances noted during this inspection.

This inspection has revealed a serious regulatory problem involving the mammography operations at your facility. Under a United States Federal Law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for conducting a mammography operation. These requirements help protect the health of women by assuring that a facility can perform quality mammography procedures. The inspection revealed the following repeat Level 2 noncompliance finding at your facility:

1. ***The Interpreting Physician ([redacted]) did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period.***

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as a repeat Level 2 noncompliance, because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement correction of problems found during your previous inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography operations and service at your facility, it represents a violation of the law which may result in ***FDA*** taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography operations.

There was also a repeat Level 3 noncompliance finding that was listed on the inspection report provided at the close of the inspection. The repeat Level 3 noncompliance finding was:

1. ***The required personnel qualification documents were unavailable during the inspection.***

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- ***The specific steps you have taken to correct the violations noted in this letter;***
- ***Each step your facility is taking to prevent the recurrence of similar violations; and***
- ***Sample records that demonstrate proper record keeping procedures.***

Please submit your response to the above issues to the attention of Arthur S. Williams, Jr., Compliance Officer, U. S. Food & Drug Administration (FDA), 158 - 15 Liberty Avenue, Jamaica, New York 11433-1034, Tel. (718)/662-5568.

Finally, you should understand there are many FDA requirements pertaining to mammography operations and procedures. This letter pertains only to the findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, U. S. Food & Drug Administration (FDA), P.O. Box 6057, Columbia, Maryland 21045-6057, Tel. (1-800/838-7715), or through the Internet at **http://www.fda.gov**.

Sincerely yours,

Jerome G. Woyshner
Acting District Director
New York District